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(54) MEDICAL VALVE WITH A VARIABLE DIAMETER SEAL

MEDIZINISCHES VENTIL MIT DICHTUNG MIT VARIABLEM DURCHMESSER

VALVE MÉDICALE DOTÉE D'UN JOINT À DIAMÈTRE VARIABLE

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(56) References cited:
EP-A2- 0 426 407
JP-A- 2000 316 986
US-A- 5 634 908
US-A1- 2011 264 105
US-B1- 6 458 103
US-B1- 6 572 590

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Description

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0001] The present disclosure relates generally to medical devices. In particular, the present disclosure relates to hemostatic valves and systems.

2. Description of the Prior Art

[0002] This section provides background information related to the present disclosure which is not necessarily prior art.

[0003] Numerous procedures have been developed that involve the percutaneous insertion of a medical device into a body vessel of a patient, with the medical device being introduced into the vessel by a variety of known techniques. Each of these procedures must control the flow of bodily fluids when the medical device is inserted into the body vessel. Accordingly, medical valves, such as hemostatic valves, iris valves, laproscopic ports, or the like, are often used to limit or prevent blood loss during the procedure.

[0004] Hemostatic valves often incorporate a disk valve to control fluid flow through the medical device. However, disk valves are subject to deformation with both time and use, and often can tear or become dislodged during insertion and/or withdrawal of the medical device. Furthermore, disk valves are not designed to provide an effective seal across a wide range of differently sized medical devices. Although the disk valve can be modified to accommodate these situations, such as with increased tensile and/or elongation properties, this modification leads to increased resistance, and thus require the use of excessive force, when the medical device is inserted and withdrawn through the disk valve. US 6,572,590 B1 discloses a medical valve assembly in accordance with the pre-characterizing portion of claim 1. Other exemplary hemostatic valves are disclosed in US 6,458,103 B1 and US 2011/0264105.

[0005] Iris valves can include an elastomeric sleeve that is disposed within a valve body and which is interconnected to a rotatable cap. When the cap is rotated in a first direction, an opening extending through the elastomeric sleeve is opened. Conversely, when the cap is rotated in a second opposite direction, the elastomeric sleeve is twisted and constricted to effectuate a closure of the elastomeric sleeve. However, if the operator stops the rotation, the elastomeric sleeve can revert, or recoil, back to the open position. Additionally, even when the elastomeric sleeve is held in the closed position, gaps or channels extend therethrough as a result of the twisting or infolding required to effectuate a closure. Accordingly, fluid can leak through the iris valve in the closed position. Further, the continuous twisting and constricting of the elastomeric sleeve leads to wear of the sleeve, such as through tearing.

[0006] The drawbacks associated with the existing medical valves are further exemplified when one considers that a single medical valve often is used to insert multiple medical devices during a single procedure. For example, a hemostatic valve may be used first for introducing a delivery catheter, followed by an interventional catheter. In this example, the hemostatic valve must be able to provide a hemostatic seal under a variety of conditions, i.e., accommodate a variety of different sized medical devices. Additionally, the hemostatic valve device must be able to quickly adjust to use of each of these different medical devices, otherwise significant fluid loss can occur through the medical valve.

SUMMARY OF THE INVENTION

[0007] This section provides a general summary of the disclosure and is not intended to be a comprehensive disclosure of its full scope, aspects, objectives, and/or all of its features.

[0008] A medical valve assembly for use in inserting a medical device into a body vessel of a patient includes a tube extending between a first tube end and a second tube end to define a passageway extending longitudinally along an axis between the ends. A plunger plate extends radially from the second tube end and a valve housing surrounds the tube about the second tube end. The valve housing extends from a first valve housing end to a second valve housing end and includes a flange extending radially inwardly from the second valve housing end, with the flange disposed in spaced relationship with respect to the plunger plate so as to define a distance dimension therebetween. An elastomeric seal is compressed between the plunger plate and the flange and has an inner diameter for use in establishing a variable seal of the medical valve assembly. One of the valve housing and the tube is axially movable relative to the other to vary the distance between the plunger plate and the flange and adjust the inner diameter of the elastomeric seal for variably sealing the medical valve assembly to a variety of differently sized medical devices. A manual actuator is provided to controllably vary the distance dimension between the valve housing and the tube for proportionately varying a compression load applied to the elastomeric seal. In other words, axial movement of one of the valve housing or the tube relative to the other varies the compression load and allows the inner diameter of the elastomeric seal to be varied or adjusted in size. As a result, the size of the inner diameter of the elastomeric seal is able to be quickly and easily adjusted by a user to allow the medical valve assembly to be used with a variety of differently sized medical devices, even during the same procedure.

[0009] Further areas of applicability will become apparent from the description provided herein. The description and specific examples in this summary are intended for purposes of illustration only and are not intended to

limit the scope of the present disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] The drawings described herein are for illustrative purposes only of selected embodiments, and are not all possible implementations and thus are not intended to limit the scope of the present disclosure.

Figure 1 is an environmental view of a first embodiment of a medical valve constructed in accordance with the principles of the present disclosure and illustrating a user interacting therewith;

Figure 2 is an environmental view of a second embodiment of the medical valve constructed in accordance with the principles of the present disclosure and illustrating the user interacting therewith;

Figure 3 is a perspective view of the first embodiment of the medical valve illustrating a scissor-type manual actuator;

Figure 4A is a cross-sectional view of the first embodiment of the medical valve illustrating a closed condition;

Figure 4B is a cross-sectional view of the first embodiment of the medical valve illustrating an open condition;

Figure 5 is a partial view taken from Figure 3 illustrating an elastomeric seal of the medical valve;

Figure 6 is a cross-sectional view of the first embodiment of the medical valve illustrating an alternative arrangement for the manual actuator;

Figure 7 is a perspective view of the first embodiment illustrating a detachable cap disposed over a pair of lever arms associated with the scissor-type manual actuator;

Figure 8 is a perspective view of the second embodiment of a medical valve constructed in accordance with the present disclosure;

Figure 9 is a cross-sectional view of the second embodiment shown in Figure 8; and

Figure 10 is a perspective view of the first embodiment illustrating an alternative arrangement of the scissor-type manual actuator.

DESCRIPTION OF THE ENABLING EMBODIMENTS

[0011] Example embodiments will now be described more fully with reference to the accompanying drawings. The example embodiments are provided so that this disclosure will be thorough and fully convey the scope to those skilled in the art. Numerous specific details are set forth such as examples of specific components, devices, mechanisms, assemblies, and methods to provide a thorough understanding of various embodiments of the present disclosure. It will be apparent to those skilled in the art that specific details need not be employed, that example embodiments may be embodied in many different forms, and that neither should be construed to limit the scope of the disclosure. With this in mind, the present disclosure is generally directed to medical valve assemblies of the type used to introduce and withdrawal a medical device (i.e., a guide wire, catheter, stent, filter, etc.) into a body vessel of a patient. In particular, each of the medical valve assemblies of the present disclosure incorporate a variable seal arrangement and a manually-operable actuator for controlling an entry dimension of the variable seal arrangement.

[0012] Referring to the Figures, wherein like numerals indicate corresponding parts throughout the several views, an environmental view of a first embodiment of a medical valve assembly **10** and a second embodiment of a medical valve assembly **10'** is generally shown in Figures 1 and 2, respectively. As illustrated therein, each medical valve assembly **10, 10'** is of the type for use with a medical device **12,** such as a guide wire, catheter, stent, filter, vessel occlusion device, or the like. As will be explained in more detail below, as the medical device **12** is inserted and guided through the medical valve assembly and into a body vessel **14** of a patient **16,** a user can manually actuate or interact with the medical valve assembly to effectuate a variable seal with variety of different sized medical devices **12.**

[0013] As best shown in Figures 4A, 4B and 9, the medical valve assemblies **10, 10'** each include a tube **20** extending between a first tube end **22** and a second tube end **24** to define a passageway **26** extending longitudinally along an axis **A** between the ends **22, 24,** with the passageway **26** being sized to receive a variety of differently sized medical devices **12.** In this instance, the first tube end **22** is a distal tube end and the second tube end is a proximal tube end **24.** A plunger plate **28** extends radially from the second tube end **24** to define an outer plunger plate surface **30** extending in spaced and parallel relationship to the axis **A.** A valve housing **32** is disposed in surrounding relationship with the tube **20** about the second tube end **24** and extends from a first valve housing end **34** to a second valve housing end **36** to overlay the outer plunger plate surface **30.** In this instance, the first valve housing end **34** is a distal valve housing end and the second valve housing end **36** is a proximal valve housing end **36.** As best shown in Figures 4A, 4B and 9, the valve housing **32** is disposed in spaced and parallel relationship with the tube **20** between the first valve housing end **34** and the plunger plate **28.**

[0014] The valve housing **32** includes a flange **38** extending radially inwardly from the second valve housing end **36.** The flange **38** is disposed in spaced relationship with the plunger plate **28** to define a distance dimension **D,** as well as a cavity **40,** extending therebetween. The flange **38** also defines an opening **42** aligned on the axis **A** and that is sized to receive a variety of differently sized medical devices **12.** An elastomeric seal **44** is installed in the cavity **40** and normally is pre-loaded or compressed between the plunger plate **28** and the flange **38.** The elastomeric seal **44** is used to establish a variable seal of the medical valve assembly **10, 10'.** In both of the first and

second embodiments of the medical valve assembly **10,10',** one of the valve housing **32** or the tube **20** is axially movable relative to the other to vary the distance dimension **D** between the plunger plate **28** and the flange **38** for effectuating an adjustment of an inner diameter **46** of the elastomeric seal **44.** In other words, the axial movement of one of the valve housing **32** or the tube **20** relative to the other results in a change in the compression load exerted on the elastomeric seal **44** which, in turn, allows the inner diameter **46** of the elastomeric seal **44** to be varied or adjusted in size. As best shown in Figures 4A, 4B and 9, when the valve housing **32** or the tube **20** is axially moved, the plunger plate **28** or the valve housing **32** axially slides relative to the other along the outer plunger plate surface **30.** In other words, the outer plunger plate surface **30** guides a sliding axial movement between the valve housing **32** and the tube **20.**

[0015] As best shown in Figures 4A, 4B, and 9, a compression member **48, 54** is disposed within the valve housing **32** and is compressed against the plunger plate **28** for normally closing or decreasing the inner diameter **46** to establish a closed position of the elastomeric seal **44.** As a result, the compression member **48, 54** is arranged to effectuate a closing or decreasing of the inner diameter **46** of the elastomeric seal **44** to establish a closed condition of the medical valve assembly **10, 10'.** In its closed condition, the elastomeric seal **44** completely isolates or seals the opening **42** of the valve housing **32** from the passageway **26** of the tube **20.** The valve housing **32** or the tube **20** is then axially movable relative to the other to alter a distance **D** between the flange **38** and the plunger plate **28** and shift the medical valve assembly **10, 10'** from the closed condition to an open/operative condition. The altered or varied distance **D** between the flange **38** and the plunger plate **28** allows the elastomeric seal **44** to expand, and as a result, the inner diameter **46** of the elastomeric seal **44** is expanded or increased to move the elastomeric seal **44** from its closed position to an open position. With the elastomeric seal **44** in its open position, the medical device **12** is positioned to be inserted serially through the opening **42,** the inner diameter **46** of the elastomeric seal **44** and the passageway **26** of the medical valve assembly **10.**

[0016] As best shown in Figures 4A and 4B, in the first embodiment of medical valve assembly **10,** the compression member **48, 54** comprises a coil spring **48** radially disposed between the valve housing **32** and the tube **20** and compressed between the first valve housing end **34** and the plunger plate **28.** However, any other suitable compression member could be utilized without departing from the scope of the subject disclosure. In a preferred embodiment, a disk **50** is slidably disposed around the tube **20** and interconnected to the first valve housing end **34** to establish a shoulder **52** extending radially inward from the valve housing **32** and which is disposed in engagement with the coil spring **48.** The coil spring **48** acts to bias the valve housing **32** towards the first tube end **22** for compressing the elastomeric seal **44** between the flange **38** and the plunger plate **28** and normally position the elastomeric seal **44** in its closed position. The valve housing **32** is then axially movable from the closed position and relative to the tube **20** to increase the distance **D** between the flange **38** and the plunger plate **28.** The increased distance **D** allows the elastomeric seal **44** to expand in an increased area of the cavity **40** disposed between the flange **38** and the plunger plate **28,** and as a result, the inner diameter **46** of the elastomeric seal **44** is expanded or increased, thereby opening the elastomeric seal **44.** The result is the establishment of the open condition of the medical valve assembly **10.**

[0017] As best shown in Figures 8 and 9, in the second embodiment of the medical valve assembly **10',** the compression member **48, 54** also comprises a coil spring **48** radially disposed between the valve housing **32** and the tube **20** and compressed between the first valve housing end **34** and the plunger plate **28.** However, any other suitable compression member could be utilized without departing from the scope of the subject disclosure. The valve housing **32** defines a shoulder **52** extending radially inward from the first valve housing end **34** and slidably disposed around the tube **20.** The shoulder **52** is disposed in engagement with the coil spring **48,** and the coil spring **48** acts to bias the valve housing **36** towards the first tube end **22.** In a preferred embodiment, the compression member **48, 54** additionally includes a leaf spring cage **54** disposed in surrounding relationship with the elastomeric seal **44.** However, any other suitable compression member could be utilized without departing from the scope of the subject disclosure. The leaf spring cage **54** extends between the plunger plate **28** and the flange **38** and is compressed therebetween by way of the compression spring **48.** The leaf spring cage **54** includes a plurality of struts **56** each extending axially along the leaf spring cage **54** and configured to fold radially inward towards the elastomeric seal **44** when the valve housing **36** is axially biased towards the first tube end **22** by the compression spring **48.** As a result, the distance **D** between the plunger plate **28** and the flange **38** is decreased, thus causing the elastomeric seal **44** to compress and reduce the inner diameter **46.** Put another way, the coil spring **48** and the leaf spring cage **54** interact to compress the elastomeric seal **44** between the flange **38** and the plunger plate **28** and normally position the elastomeric seal **44** in its closed position. As a medical device **12** is inserted through the passageway **26,** the medical device **12** engages the elastomeric seal **44** with an insertion force that is transferred or exerted radially outward on the struts **56** of the leaf spring cage **54,** causing the leaf spring cage **54** to expand and counteract the biasing force of the coil spring **48.** As a result, the distance between the plunger plate **28** and the flange **38** is increased, allowing the inner diameter **46** of the elastomeric seal **44** to expand or increase and establish the open condition of the medical valve assembly **10'.** A constrictor band **58** extends around the leaf spring cage **54** to prevent the plurality of struts **56** from engaging the valve

housing **32** when the leaf spring cage **54** is expanded by the insertion force of the medical device **12.**

[0018] As best shown in Figures 3, 4A, and 4B, the first embodiment of the medical valve assembly **10** includes a manual actuator **62** which can be connected to the valve housing **32** for allowing a user to interact with the medical valve assembly **10** and vary a size of the inner diameter **46** of the elastomeric seal **44.** Put another way, the user can interact with the manual actuator **62** to overcome the bias of the compression member **48** and move the valve housing **32** relative to the tube **20** along the axis **A** towards the second tube end **24.** As a result, the manual actuator **62** allows the user to manually establish the open condition of the medical valve assembly **10.** As best shown in Figure 6, in the alternative embodiment, the manual actuator **62** can include a trigger arm **60** extending radially from the valve housing **32.** In this situation, the user can pull back on the trigger arm **60** to establish the open condition of the medical valve assembly **10.** In other words, a user can pull back the trigger arm **60** to vary the bias on the plunger plate **28.**

[0019] As best shown in Figures 3 and 4, the manual actuator **62** can include a pair of lever arms **63** interconnected between the tube **20** and the valve housing **32** by way of a pair of lever linkages **64.** As best shown in Figure 3, each lever arm **63** includes a first pivot **66** extending radially from the tube **20** and each lever linkage **64** includes a second pivot **68** extending radially from the valve housing **32.** The pair of lever arms **63** are pivotably connected to the tube **20** by the first pivots **66** and the pair of lever linkages **64** are pivotably connected to the valve housing by the second pivots **68** with each of the lever linkages **64** extending from the respective second pivot **68** to engage one of the respective lever arms **63.** As best shown in Figure 7, in a preferred embodiment, each of the lever arms **63** can also define a track **70** for receipt of the respective lever linkage **64** when the lever linkages **64** are disposed in abutting relationship with the lever arms **63.** This arrangement of the lever arms **63** and the lever linkages **64** allows the user to squeeze or compress the pair of lever arms **63** with a specific force to axially advance the valve housing **32** by way of the lever linkages **64.** As a result, the transferred force effectuates the increase in the distance **D** between the plunger plate **28** and the flange **38,** and thus the increase in the inner diameter **46** of the elastomeric seal **44.** Put another way, a user can radially squeeze or compress the lever arms **63** to release compression on the elastomeric seal **44** and increase the inner diameter **46** of the elastomeric seal **44** from the closed condition to a desired size of the inner diameter **46** based on an amount of radial squeeze.

[0020] As best shown in Figure 10, in an alternative arrangement the pair of lever arms **63** can be interconnected between the tube **20** and the valve housing **32** by way of a pair of plates **65.** In a preferred embodiment, each lever arm **63** includes a plate **65** which extends radially therefrom and which defines a cam slot **67** for receiving the second pivot **68** extending radially from the valve housing **32.** This arrangement of the lever arms **63** and the plates **65** allows the user to squeeze or compress the pair of lever arms **63** with a specific force to slide the second pivot **68** along the cam slots **67** and axially advance the valve housing **32** by way of the plates **65.** As a result, the transferred force effectuates the increase in the distance **D** between the plunger plate **28** and the flange **38,** and thus the increase in the inner diameter **46** of the elastomeric seal **44.** Put another way, a user can radially squeeze or compress the lever arms **63** to release compression on the elastomeric seal **44** and increase the inner diameter **46** of the elastomeric seal **44** from the closed condition to a desired size of the inner diameter **46** based on an amount of radial squeeze.

[0021] As best shown in Figure 7, a detachable cap **72** can be snapped or disposed over the second valve housing end **36** of the valve housing **32** to hold the pair of lever arms **63** in the radially compressed position when the medical valve assembly **10** is not in use. When the detachable cap **72** is in place, it keeps the elastomeric seal **44** in the open position, and thus increases the shelf life by reducing material creep, material sticking, and/or the distorting of the elastomeric seal **44.**

[0022] As best shown in Figure 5, the elastomeric seal **44** can include an inner portion **74** and an outer portion **76** disposed axially outwardly from the inner portion **74.** In a preferred embodiment, the inner portion **74** is made from a first material having a first durometer value and the outer portion **76** is made from a second material having a second durometer value being greater than the first durometer value. In other words, the elastomeric seal **44** includes an outside portion **76** that is harder than an inside portion **74.** As further shown in Figures 4A and 4B, the outer portion **76** of the elastomeric seal **44** is disposed in compressed relationship with the plunger plate **28** and the flange **38.** In a preferred embodiment, the plunger plate **28** and the flange **38** can include curved portions **78** to improve the retention and compression of the outer portions **76** of the elastomeric seal **44.**

[0023] As best shown in Figure 4, the tube **20** has a tapered portion **80** disposed adjacent the first tube end **22** for fitting a sheath over the tube **20.** The tube **20** includes threads **82** disposed adjacent the first tube end **22** and a nose cap **84** is threadingly secured to the first tube end **22** for establishing a compression fit of the sheath between the nose cap **84** and the tapered portion **80** of the tube **20.** Although not expressly shown, a wiper seal can be disposed within the passageway **26** between the elastomeric seal **44** and the first tube end **22** to provide a level of hemostasis around a larger device while the elastomeric seal **44** is opened for insertion of the medical device **12.** Alternatively, as best shown in Figure 5, a wiper seal **86** can be incorporated into the elastomeric seal **44** and extends radially inward from one of the outside portions **76.** As a result, when the elastomeric seal **44** is inserted in the cavity **40,** the wiper seal **86** is disposed adjacent the opening **42** of the valve housing **32.**

[0024] It will be appreciated by those skilled in the art

that the medical valve assembly **10'** shown in Figures 8 and 9 can be equipped with the compression type manual actuator **62** shown in Figures 3, 4 and 7 or, in the alternative, the pull-type manual actuator **60** shown in Figure 6. Likewise, alternative configurations are contemplated for manual actuators that function to controllably vary the relative axial position between two components for proportionately controlling the compression load applied to an elastomeric seal to regulate an internal opening dimension defined thereby.

[0025] The foregoing description of the embodiments has been provided for purposes of illustration and description. It is not intended to be exhaustive or to limit the disclosure. Individual elements or features of a particular embodiment are generally not limited to that particular embodiment, but, where applicable, are interchangeable and can be used in a selected embodiment, even if not specifically shown or described. The same may also be varied in many ways. Such variations are not to be regarded as a departure from the disclosure, and all such modifications are intended to be included within the scope of the disclosure.

Claims

1. A medical valve assembly (10) for use in inserting a medical device (12) into a body vessel (14) of a patient, comprising:

a tube (20) extending between a first tube end (22) and a second tube end (24) to define a passageway (26) extending along a longitudinal axis (A) between said ends;
a plunger plate (28) extending radially from said second tube end (24) of said tube (20);
a valve housing (32) extending from a first valve housing end (34) to a second valve housing end (36);
said valve housing (32) including a flange (38) extending radially inwards from said second valve housing end (36) and disposed in spaced relationship with said plunger plate (28) to define a distance extending therebetween;
an elastomeric seal (44) compressed between said plunger plate (28) and said flange (38) and having an inner diameter (46) for use in establishing a variable seal of the medical valve assembly (10); and
one of said valve housing (32) and said tube (20) axially movable relative to the other to vary the distance between said plunger plate (28) and said flange (38) and adjust said inner diameter (46) of said elastomeric seal (44) for variably sealing the medical valve assembly (10) to a variety of differently sized medical devices;
wherein said valve housing (32) surrounds said tube (20) about said second tube end (24);
a compression member (48, 54) disposed within said valve housing (32) **characterised in that** the compression member (48, 54) is biased against said plunger plate (28) for decreasing said inner diameter to establish a closed condition of the medical valve assembly (10).

2. The medical valve assembly (10) as set forth in claim 1, wherein said plunger plate (28) defines a plunger plate surface (30) extending in spaced and parallel relationship to said longitudinal axis (A) and said valve housing (32) overlays said plunger plate surface (30) for allowing one of said plunger plate (28) and said valve housing (32) to slide relative to one another along said plunger plate surface (30) during said axial movement.

3. The medical valve assembly (10) as set forth in claim 1, wherein elastomeric seal (44) includes an inner portion (74) and an outer portion (76) disposed axially outward from said inner portion (74) and disposed in abutting relationship one of said plunger plate (28) and said flange (38), and said inner portion (74) having a first durometer value and said outer portion (76) having a second durometer value being greater than said first durometer value.

4. The medical valve assembly (10) as set in claim 1, wherein said compression member includes a coil spring (48) radially disposed between said valve housing (32) and said tube (20) and compressed between said first valve housing end (34) and said plunger plate (28) to bias said valve housing (32) towards said first tube end (22) and compress said elastomeric seal (44) between said flange (38) and said plunger plate (28) to establish the closed condition of the medical valve assembly (10), in particular wherein said compression member further includes a leaf spring cage (54) surrounding said tubular elastomeric seal (44) and compressed between said plunger plate (28) and said flange (20).

5. The medical valve assembly (10) as set forth in claim 1, further comprising a disk (50) slidably disposed around said tube (20) and interconnected to said first valve housing end (34) to establish a shoulder extending radially inward from said valve housing (32) and disposed in engagement with said compression member, wherein said compression member is a spring (48).

6. The medical valve assembly (10) as set forth in claim 1, wherein said valve housing (32) is movable relative to said tube (20) to increase the distance between said flange (38) and said plunger plate (28) to allow said tubular elastomeric seal (44) to expand and increase said inner diameter (46) for establishing an open condition of the medical valve assembly

(10).

7. The medical valve assembly (10) as set forth in claim 6, further comprising a manual actuator (62) connected to said valve housing (32) for allowing a user to interact with said manual actuator (62) and overcome the bias of said compression member, wherein said compression member is a spring (48), to move said valve housing (32) relative to said tube (20) along said axis (A) towards said second tube end (24) and vary said inner diameter (46) of said elastomeric seal (44), in particular wherein said manual actuator (62) includes a trigger arm (60) extending radially from said valve housing (32).

8. The medical valve assembly (10) as set forth in claim 7, further comprising:

a first pivot (66) extending radially from said tube (20) and a second pivot (68) extending radially from said valve housing (32);
said manual actuator (62) including a pair of lever arms (63) pivotably connected to said first pivot (66) and a pair of lever linkages (64) pivotably connected to said second pivot (68); and
wherein each of said lever linkages (64) extend from said second pivot (68) to engage one of said respective levers (63) for allowing the user to radially compress said pair of lever arms (63) with a force to effectuate the increase in the distance between said plunger plate (28) and said flange (38), in particular wherein each of said lever arms (63) define a track (70) for receipt of said respective lever linkage (64) when disposed in abutting relationship therewith.

9. The medical valve assembly (10) as set forth in claim 8, further comprising a detachable cap (72) disposed over said second valve housing end (36) of said valve housing (32) to snap said pair of lever arms (63) in the radially compressed position and keep said elastomeric seal (44) in the open position.

10. The medical valve assembly (10) as set forth in claim 4, wherein said leaf spring cage (54) includes a plurality of struts (56) each extending axially along said leaf spring cage (54) and configured to fold radially inward towards said valve housing (32) is axially biased towards said first tube end (22) by said compression spring (48) to decrease the distance between said plunger plate (28) and said flange (38) and compress said elastomeric seal (44) for decreasing said inner diameter (46) and establishing a closed condition of the medical valve assembly (10), in particular further comprising a constrictor band (58) extending around said leaf spring cage (54) to prevent said plurality of struts (56) from engaging said valve housing (32) when said leaf spring cage (54) is expanded by an insertion force of a medical device (12).

11. The medical valve assembly (10) as set forth in claim 1, further comprising:

said tube (20) defining a tapered portion (80) disposed adjacent said first tube end (22) for fitting a sheath over said tube (20);
said tube (20) including threads (82) disposed adjacent said first tube end (22); and
a nose cap (84) threadingly secured to said first tube end (22) for establishing a compression fit of the sheath between said cap (84) and said tapered portion (80) of said tube (20).

12. The medical valve assembly (10) as set forth in claim 1, wherein said flange (20) defines an opening (42) aligned on said axis (A) and sized to receive the medical device (12), in particular wherein said elastomeric seal (44) includes an inner portion (74) comprised of a first material having a first durometer value and an outer portion (76) comprised of a second material having a second durometer value being greater than said first durometer value, and a wiper seal (86) extends radially from said outside portion (76) and is disposed adjacent said opening (42) of the valve housing (32).

13. The medical valve assembly (10) as set forth in claim 3 or 12, wherein the plunger plate (28) and the flange (38) include curved portions (78) to improve the retention and compression of the outer portions (76) of the elastomeric seal (44).

Patentansprüche

1. Medizinische Ventilbaugruppe (10) zur Verwendung beim Einsetzen einer medizinischen Vorrichtung (12) in ein Körpergefäß (14) eines Patienten, umfassend:

ein Rohr (20), das sich zwischen einem ersten Rohrende (22) und einem zweiten Rohrende (24) erstreckt, um einen sich entlang einer Längsachse (A) zwischen den Enden erstreckenden Durchgang (26) zu definieren;
eine Plungerplatte (28), die sich radial von dem zweiten Rohrende (24) des Rohres (20) erstreckt;
ein Ventilgehäuse (32), das sich von einem ersten Ventilgehäuseende (34) zu einem zweiten Ventilgehäuseende (36) erstreckt;
wobei das Ventilgehäuse (32) einen Flansch (38) aufweist, der sich radial einwärts von dem zweiten Ventilgehäuseende (36) erstreckt und in beabstandeter Beziehung mit der Plunger-

platte (28) angeordnet ist, um eine sich dazwischen erstreckende Distanz zu definieren;
eine elastomere Dichtung (44), die zwischen der Plungerplatte (28) und dem Flansch (38) komprimiert ist und einen Innendurchmesser (46) zur Verwendung bei der Herstellung einer variablen Dichtung der medizinischen Ventilbaugruppe (10) aufweist; und
wobei eines von dem Ventilgehäuse (32) und dem Rohr (20) axial relativ zu dem anderen bewegbar ist, um die Distanz zwischen der Plungerplatte (28) und dem Flansch (38) zu variieren und den Innendurchmesser (46) der elastomeren Dichtung (44) zum variablen Abdichten der medizinischen Ventilbaugruppe (10) an einer Vielzahl verschieden bemessener medizinischer Vorrichtungen einzustellen;
wobei das Ventilgehäuse (32) das Rohr (20) um das zweite Rohrende (24) umgibt;
ein Kompressionselement (48, 54), das in dem Ventilgehäuse (32) angeordnet ist, **dadurch gekennzeichnet, dass** das Kompressionselement (48, 54) gegen die Plungerplatte (28) zum Verringern des Innendurchmessers vorgespannt ist, um einen geschlossenen Zustand der medizinischen Ventilbaugruppe (10) herzustellen.

2. Medizinische Ventilbaugruppe (10) nach Anspruch 1, wobei die Plungerplatte (28) eine Plungerplattenfläche (30) definiert, die sich in beabstandeter und paralleler Beziehung zu der Längsachse (A) erstreckt, und das Ventilgehäuse (32) über der Plungerplattenfläche (30) liegt, um zu ermöglichen, dass eines von der Plungerplatte (28) und dem Ventilgehäuse relativ zu dem anderen entlang der Plungerplattenfläche (30) während der axialen Bewegung gleitet.

3. Medizinische Ventilbaugruppe (10) nach Anspruch 1, wobei die elastomere Dichtung (44) einen Innenabschnitt (74) und einen Außenabschnitt (76) aufweist, der axial auswärts von dem Innenabschnitt (74) angeordnet und in angrenzender Beziehung an einem der Plungerplatte (28) und des Flansches (38) angeordnet ist, und wobei der Innenabschnitt (74) einen ersten Durometerwert aufweist und der Außenabschnitt (76) einen zweiten Durometerwert aufweist, der größer als der erste Durometerwert ist.

4. Medizinische Ventilbaugruppe (10) nach Anspruch 1, wobei das Kompressionselement eine Schraubenfeder (48) aufweist, die radial zwischen dem Ventilgehäuse (32) und dem Rohr (20) angeordnet und zwischen dem ersten Ventilgehäuseende (34) und der Plungerplatte (28) komprimiert ist, um das Ventilgehäuse (32) zu dem ersten Rohrende (22) vorzuspannen und die elastomere Dichtung (44) zwischen dem Flansch (38) und der Plungerplatte (28) zu komprimieren, um den geschlossenen Zustand der medizinischen Ventilbaugruppe (10) herzustellen, wobei insbesondere das Kompressionselement ferner einen Blattfederkäfig (54) aufweist, der die rohrförmige elastomere Dichtung (44) umgibt und zwischen der Plungerplatte (28) und dem Flansch (20) komprimiert ist.

5. Medizinische Ventilbaugruppe (10) nach Anspruch 1, ferner mit einer Scheibe (50), die gleitend um das Rohr (20) angeordnet und mit dem ersten Ventilgehäuseende (34) verbunden ist, um eine Schulter herzustellen, die sich radial einwärts von dem Ventilgehäuse (32) erstreckt und in Eingriff mit dem Kompressionselement angeordnet ist, wobei das Kompressionselement eine Feder (48) ist.

6. Medizinische Ventilbaugruppe (10) nach Anspruch 1, wobei das Ventilgehäuse (32) relativ zu dem Rohr (20) bewegbar ist, um die Distanz zwischen dem Flansch (38) und der Plungerplatte (28) anzuheben und zu ermöglichen, dass sich die rohrförmige elastomere Dichtung (44) ausdehnt und den Innendurchmesser (46) zur Herstellung eines offenen Zustandes der medizinischen Ventilbaugruppe (10) erhöht.

7. Medizinische Ventilbaugruppe (10) nach Anspruch 6, ferner mit einem manuellen Aktor (62), der mit dem Ventilgehäuse (32) verbunden ist, um zu ermöglichen, dass ein Nutzer mit dem manuellen Aktor (62) interagieren und die Vorspannung des Kompressionselements überwinden kann, wobei das Kompressionselement eine Feder (48) ist, um das Ventilgehäuse (32) relativ zu dem Rohr (20) entlang der Achse (A) zu dem zweiten Rohrende (24) zu bewegen und den Innendurchmesser (46) der elastomeren Dichtung (44) zu variieren, wobei insbesondere der manuelle Aktor (62) einen Auslösearm (60) aufweist, der sich radial von dem Ventilgehäuse (32) erstreckt.

8. Medizinische Ventilbaugruppe (10) nach Anspruch 7, ferner mit:

einer ersten Drehstelle (66), die sich radial von dem Rohr (20) erstreckt, und einer zweiten Drehstelle (68), die sich radial von dem Ventilgehäuse (32) erstreckt;
wobei der manuelle Aktor (62) ein Paar von Hebelarmen (63) aufweist, die schwenkend mit der ersten Drehstelle (60) verbunden sind, und ein Paar von Hebelgestängen (64) aufweist, die schwenkend mit der zweiten Drehstelle (68) verbunden sind; und
wobei jedes der Hebelgestänge (64) sich von der zweiten Drehstelle (68) zum Eingriff mit einem der jeweiligen Hebel (63) erstreckt, um zu

ermöglichen, dass der Nutzer das Paar von Hebelarmen (63) mit einer Kraft radial komprimieren kann, um die Zunahme der Distanz zwischen der Plungerplatte (28) und dem Flansch (38) zu bewirken, wobei insbesondere jeder der Hebelarme (63) eine Bahn (70) zur Aufnahme des jeweiligen Hebelgestänges (64) bei Anordnung in anliegender Beziehung damit definiert.

9. Medizinische Ventilbaugruppe (10) nach Anspruch 8, ferner mit einer ablösbaren Kappe (72), die über dem zweiten Ventilgehäuseende (36) des Ventilgehäuses (32) angeordnet ist, um das Paar von Hebelarmen (63) in der radial komprimierten Position zu schnappen und die elastomere Dichtung (44) in der offenen Position zu halten.

10. Medizinische Ventilbaugruppe (10) nach Anspruch 4, wobei der Blattfederkäfig (54) eine Mehrzahl von Streben (56) aufweist, die sich jeweils axial entlang des Blattfederkäfigs (54) erstrecken und derart konfiguriert sind, sich radial einwärts zu dem Ventilgehäuse (32) zu falten, axial zu dem ersten Rohrende (22) durch die Kompressionsfeder (48) vorgespannt ist, um die Distanz zwischen der Plungerplatte (28) und dem Flansch (38) zu vermindern und die elastomere Dichtung (44) zur Verminderung des Innendurchmessers (46) und Herstellung eines geschlossenen Zustandes der medizinischen Ventilbaugruppe (10) zu komprimieren, ferner insbesondere mit einem Beschränkungsband (58), das sich um den Blattfederkäfig (54) erstreckt, um einen Eingriff der Mehrzahl von Streben (56) mit dem Ventilgehäuse (32) zu verhindern, wenn der Blattfederkäfig (54) durch eine Einsetzkraft einer medizinischen Vorrichtung (12) ausgedehnt ist.

11. Medizinische Ventilbaugruppe (10) nach Anspruch 1, ferner umfassend, dass:

das Rohr (20) einen verjüngten Abschnitt (80) definiert, der benachbart dem ersten Rohrende (22) zum Einpassen einer Umhüllung über das Rohr (20) angeordnet ist;
das Rohr (20) ein Gewinde (82) aufweist, das benachbart dem ersten Rohrende (22) angeordnet ist; und
eine Nasenkappe (84) auf das erste Rohrende (22) zum Herstellen einer Presspassung der Umhüllung zwischen der Kappe (84) und dem verjüngten Abschnitt (80) des Rohres (20) geschraubt ist.

12. Medizinische Ventilbaugruppe (10) nach Anspruch 1, wobei der Flansch (20) eine Öffnung (42) definiert, die an der Achse (A) ausgerichtet und derart bemessen ist, die medizinische Vorrichtung (12) aufzunehmen, wobei insbesondere die elastomere Dichtung (44) einen Innenabschnitt (74), der aus einem ersten Material mit einem ersten Durometerwert besteht, und einen Außenabschnitt (76) aufweist, der aus einem zweiten Material mit einem zweiten Durometerwert besteht, der größer als der erste Durometerwert ist, und sich eine Wischerdichtung (86) radial von dem Außenabschnitt (76) erstreckt und benachbart der Öffnung (42) des Ventilgehäuses (32) angeordnet ist.

13. Medizinische Ventilbaugruppe (10) nach einem der Ansprüche 3 oder 12, wobei die Plungerplatte (28) und der Flansch (38) gekrümmte Abschnitte (78) aufweisen, um die Rückhaltung und Kompression der Außenabschnitte (76) der elastomeren Dichtung (44) zu verbessern.

Revendications

1. Ensemble de valve médicale (10) destiné à être utilisé pour introduire un dispositif médical (12) dans un vaisseau corporel (14) d'un patient, comportant :

un tube (20) s'étendant entre une première extrémité de tube (22) et une second extrémité de tube (24) pour définir un passage (26) s'étendant le long d'un axe longitudinal (A) entre lesdites extrémités ;
une plaque de piston (28) s'étendant radialement depuis ladite seconde extrémité de tube (24) dudit tube (20) ;
un boîtier de valve (32) s'étendant depuis une première extrémité de boîtier de valve (34) vers une seconde extrémité de boîtier de valve (36) ; ledit boîtier de valve (32) incluant une bride (38) s'étendant radialement vers l'intérieur depuis ladite seconde extrémité de boîtier de valve (36) et agencée de manière espacée par rapport à ladite plaque de piston (28) pour définir une distance s'étendant entre celles-ci ;
un joint élastomère (44) comprimé entre ladite plaque de piston (28) et ladite bride (38) et ayant un diamètre intérieur (46), destiné à être utilisé pour réaliser une étanchéité variable de l'ensemble de valve médicale (10) ; et
un desdits éléments parmi ledit boîtier de valve (32) et ledit tube (20) étant axialement mobile par rapport à l'autre pour varier la distance entre ladite plaque de piston (20) et ladite bride (38) et pour régler le diamètre intérieur (46) dudit joint élastomère (44) pour étancher de manière variable l'ensemble de valve médicale (10) à une gamme de différentes tailles de dispositifs médicaux ;
dans lequel ledit boîtier de valve (32) entoure ledit tube (20) autour de ladite seconde extrémité de tube (24) ;

un élément de compression (48, 54) agencé à l'intérieur dudit boîtier de valve (32), **caractérisé en ce que** l'élément de compression (48, 54) est sollicité contre ladite plaque de piston (28) pour réduire ledit diamètre intérieur pour établir une condition fermée de l'ensemble de valve médicale (10).

2. Ensemble de valve médicale (10) selon la revendication 1, dans lequel ladite plaque de piston (28) définit une surface de plaque de piston (30) s'étendant de manière espacée et parallèlement audit axe longitudinal (A) et ledit boîtier de valve (32) recouvrant ladite surface de plaque de piston (30) pour permettre à l'un desdits éléments parmi ladite plaque de piston (28) et ledit boîtier de valve (32) de coulisser l'un par rapport à l'autre le long de ladite surface de plaque de piston (30) pendant ledit mouvement axial.

3. Ensemble de valve médicale (10) selon la revendication 1, dans lequel le joint élastomère (44) inclut une partie intérieure (74) et une partie extérieure (76) agencée axialement en dehors de la partie intérieure (74) et agencée en relation de butée avec une parmi ladite plaque de piston (28) et de ladite bride (38), et ladite partie intérieure (74) ayant une première valeur de dureté et ladite partie extérieure (76) ayant une second valeur de dureté qui est supérieure à ladite première valeur de dureté.

4. Ensemble de valve médicale (10) selon la revendication 1, dans lequel ledit élément de compression inclut un ressort hélicoïdal (48) qui est radialement agencé entre ledit boîtier de valve (32) et ledit tube (20) et comprimé entre la première extrémité de du boîtier de valve (34) et ladite plaque de piston (28) pour solliciter ledit boîtier de valve (32) vers ladite première extrémité de tube (22) et comprime ledit joint élastomère (44) entre ladite bride (38) et ladite plaque de piston (28) pour établir la condition fermée de l'ensemble de valve médicale (10), en particulier dans lequel ledit élément de compression inclut en outre une cage à ressort à lames (54) entourant ledit joint élastomère (44) tubulaire et comprimée entre ladite plaque de piston (28) et ladite bride (38).

5. Ensemble de valve médicale (10) selon la revendication 1, comportant en outre un disque (50) agencé de manière coulissante autour dudit tube (20) et relié à ladite première extrémité de boîtier de valve (34) pour former un épaulement s'étendant radialement vers l'intérieur depuis ledit boîtier de valve (32) et agencé en engagement avec ledit élément de compression, dans lequel l'élément de compression est un ressort (48).

6. Ensemble de valve médicale (10) selon la revendication 1, dans lequel ledit boîtier de valve (32) est mobile par rapport audit tube (20) pour augmenter la distance entre ladite bride (38) et ladite plaque de piston (28) pour permettre au joint élastomère (44) de s'étendre et d'augmenter ledit diamètre intérieur (46) pour établir une condition ouverte de l'ensemble de valve médicale (10).

7. Ensemble de valve médicale (10) selon la revendication 6, comportant en outre un actionneur manuel (62) relié audit boîtier de valve (32) pour permettre à un utilisateur d'interagir avec ledit actionneur manuel (62) et de surmonter la sollicitation dudit élément de compression, dans lequel ledit élément de compression est un ressort (48) pour déplacer ledit boîtier de valve (32) par rapport audit tube (20) le long dudit axe (A) vers ladite second extrémité de tube (24) et pour faire varier ledit diamètre intérieur (46) dudit joint élastomère (44), en particulier dans lequel ledit actionneur manuel (62) inclut un bras de déclenchement (60) s'étendant radialement depuis ledit boîtier de valve (32).

8. Ensemble de valve médicale (10) selon la revendication 7, comportant en outre :

un premier pivot (66) s'étendant radialement depuis ledit tube (20) et un second pivot (68) s'étendant radialement depuis ledit boîtier de valve (32) ;
ledit actionneur manuel (62) incluant une paire de bras de levier (63) reliés en pivotement audit premier pivot (66) et une paire de tiges de levier (64) reliées en pivotement audit second pivot (68) ; et
dans lequel chacune desdites tiges de levier (64) s'étend depuis ledit second pivot (68) pour engager un desdits leviers (63) respectifs pour permettre à l'utilisateur de comprimer radialement ladite paire de bras de levier (63) avec une force pour effectuer une augmentation de la distance entre ladite plaque de piston (28) et ladite bride (38), en particulier dans lequel chacun desdits bras de levier (63) définit une voie (70) pour recevoir ladite tige de levier (64) respective lorsqu'ils sont agencés en butée avec celle-ci.

9. Ensemble de valve médicale (10) selon la revendication 8, comportant en outre un capuchon (72) détachable agencé sur ladite seconde extrémité de boîtier de valve (36) dudit boîtier de valve (32) pour encliqueter ladite paire de bras de levier (63) dans la position radialement comprimée et pour maintenir ledit joint élastomère (44) dans la position ouverte.

10. Ensemble de valve médicale (10) selon la revendication 4, dans lequel ladite cage de ressort à lames (54) inclut une pluralité d'entretoises (56) qui s'éten-

dent chacune axialement le long de ladite cage de ressort à lames (54) et sont configurées pour se replier radialement vers l'intérieur vers ledit boîtier de valve (32), elle est axialement sollicitée vers ladite première extrémité de tube (22) par ledit ressort de compression (48) pour réduire la distance entre ladite plaque de piston (28) et ladite bride (38) et pour comprimer ledit joint élastomère (44) afin de réduire ledit diamètre intérieur (46) et d'établir une condition fermée de l'ensemble de valve médicale (10), comportant en outre en particulier une bande d'étranglement (58) s'étendant autour de ladite cage de ressort à lames (54) pour éviter que la pluralité d'entretoises (56) viennent engager ledit boîtier de valve (32) lorsque ladite cage de ressort à lames (54) est étendue par une force d'insertion du dispositif médical (12).

11. Ensemble de valve médicale (10) selon la revendication 1, comportant en outre :

ledit tube (20) définissant une partie effilée (80) agencée de manière adjacente à ladite première extrémité de tube (22) pour fixer une gaine sur ledit tube (20) ;
ledit tube (20) incluant des pas de vis (82) agencés de manière adjacente à ladite première extrémité de tube (22) et
une coiffe (84) fixée par vissage sur ladite première extrémité de tube (22) pour établir une fixation par compression de la gaine entre ladite coiffe (84) et ladite partie effilée (80) dudit tube (20).

12. Ensemble de valve médicale (10) selon la revendication 1, dans lequel ladite bride (38) définit une ouverture (42) alignée sur ledit axe (A) et est dimensionnée pour recevoir ledit dispositif médical (12), dans lequel en particulier ledit joint élastomère (44) inclut une partie intérieure (74) constituée d'un premier matériau ayant une première valeur de dureté et une partie extérieure (76) constituée d'un second matériau ayant une seconde valeur de dureté qui est supérieure à la première valeur de dureté, et un joint racleur (86) s'étend radialement depuis ladite partie extérieure (76) et est agencé de manière adjacente à ladite ouverture (42) du boîtier de valve (32).

13. Ensemble de valve médicale (10) selon la revendication 3 ou 12, dans lequel la plaque de piston (28) et la bride (38) incluent des parties incurvées (78) pour améliorer la retenue et la compression des parties extérieures (76) du joint élastomère (44).

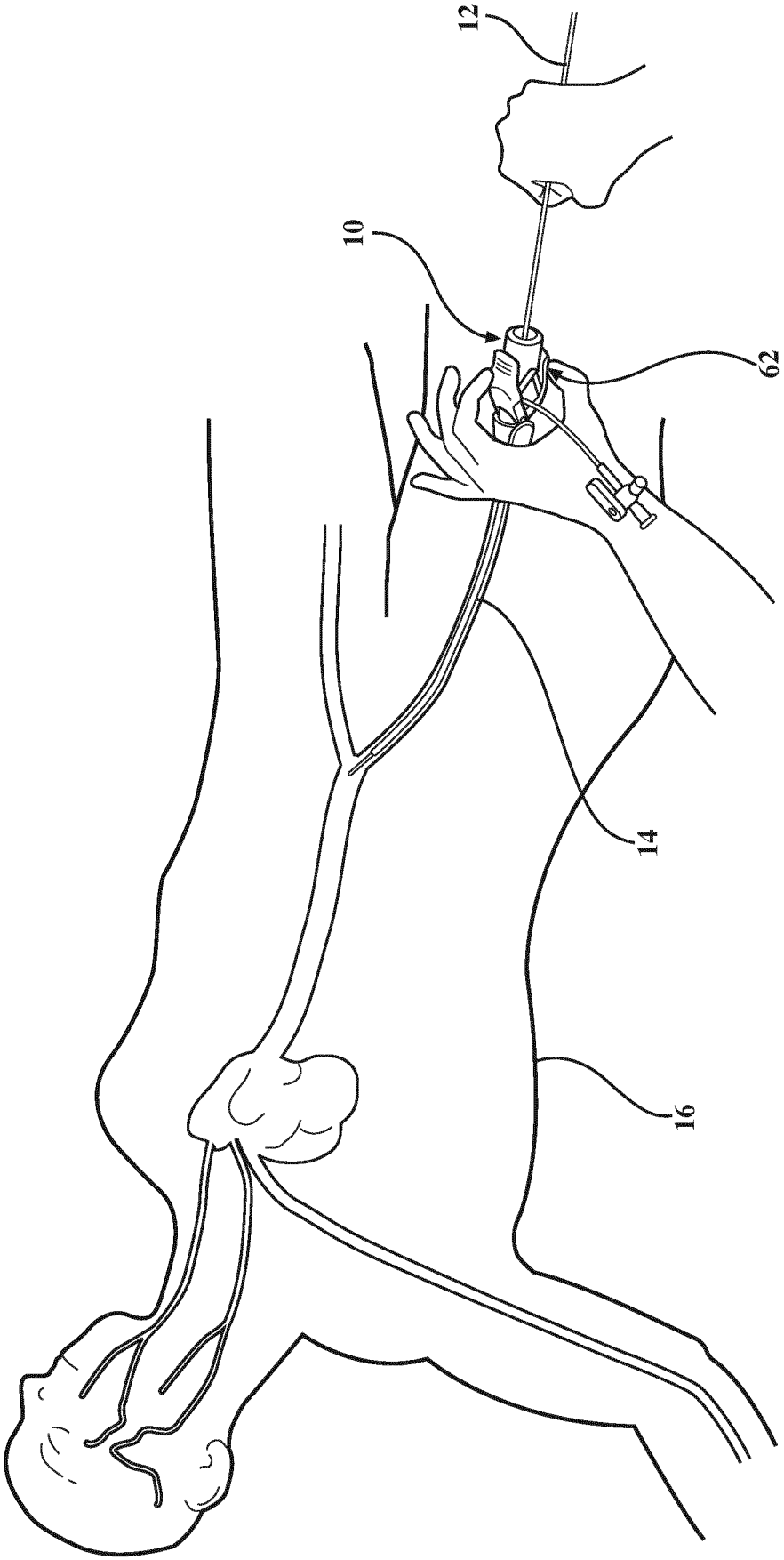

FIG. 1

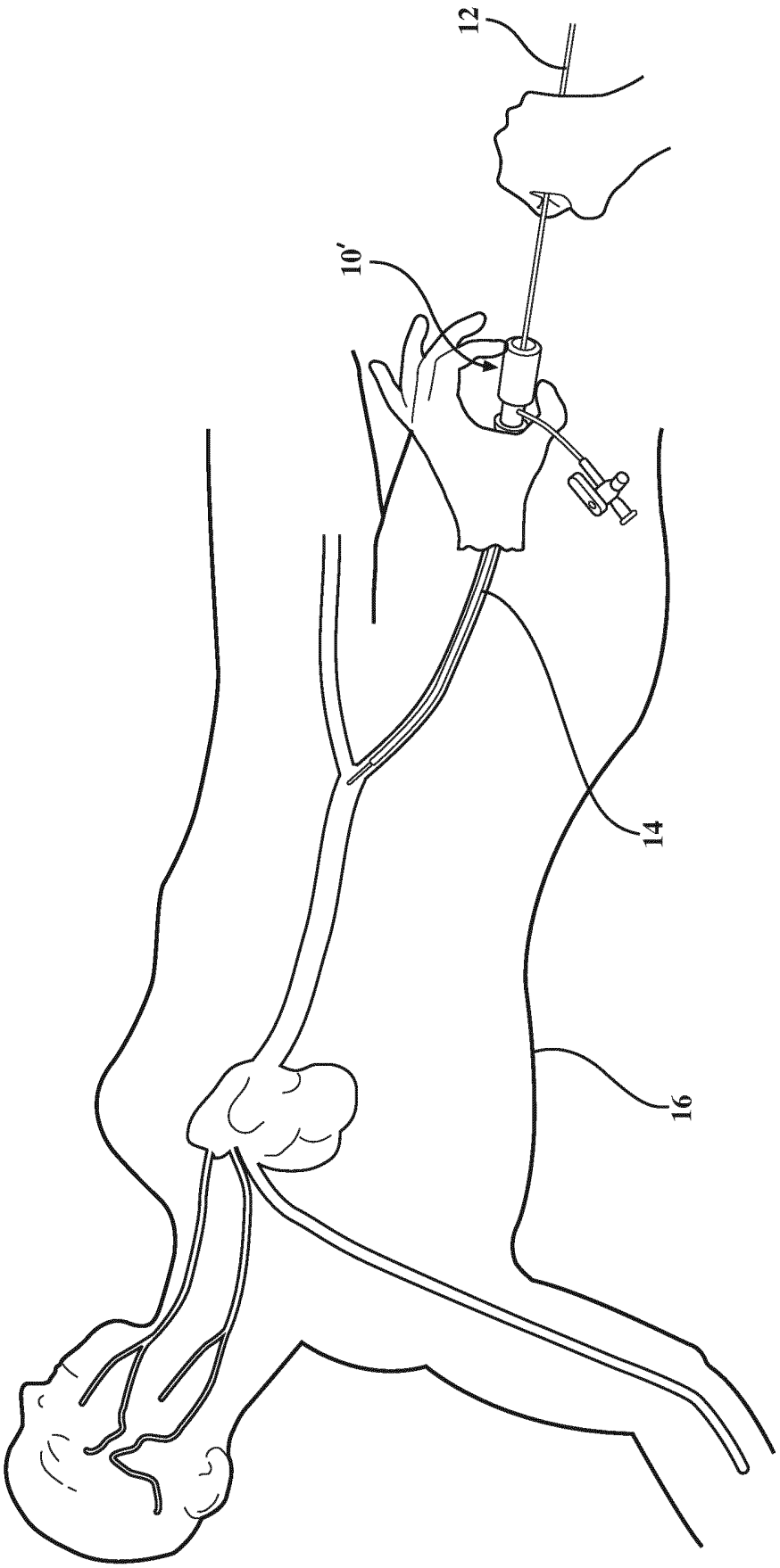

FIG. 2

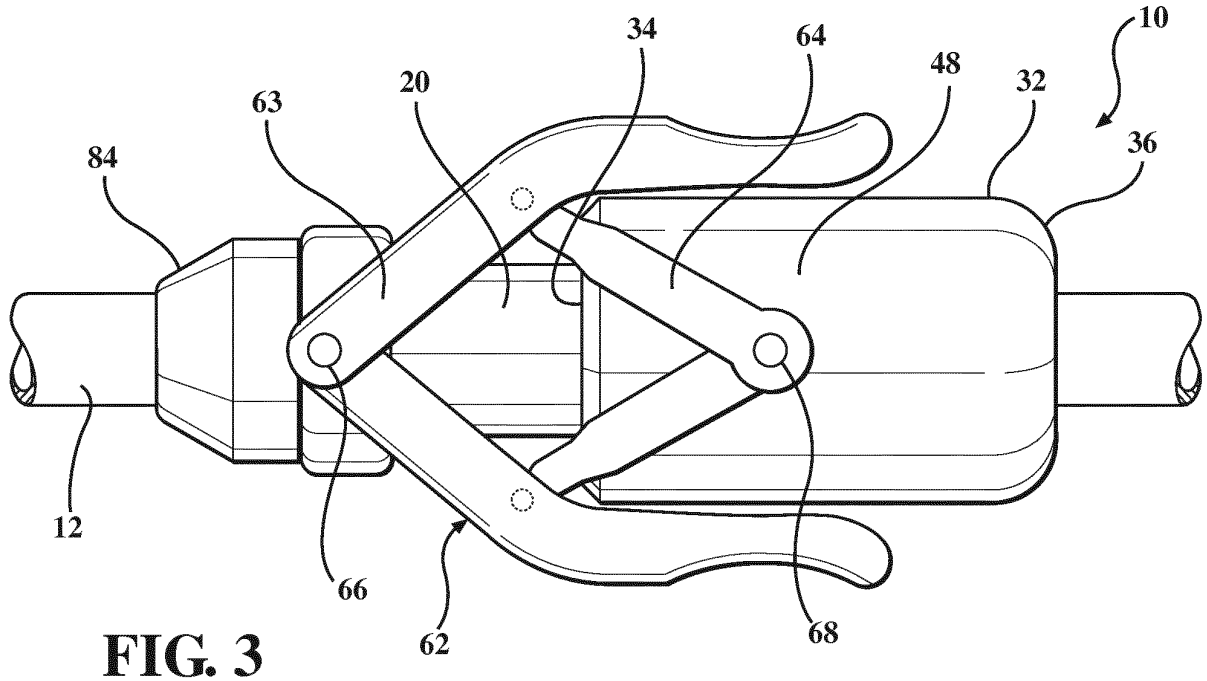
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FIG. 3

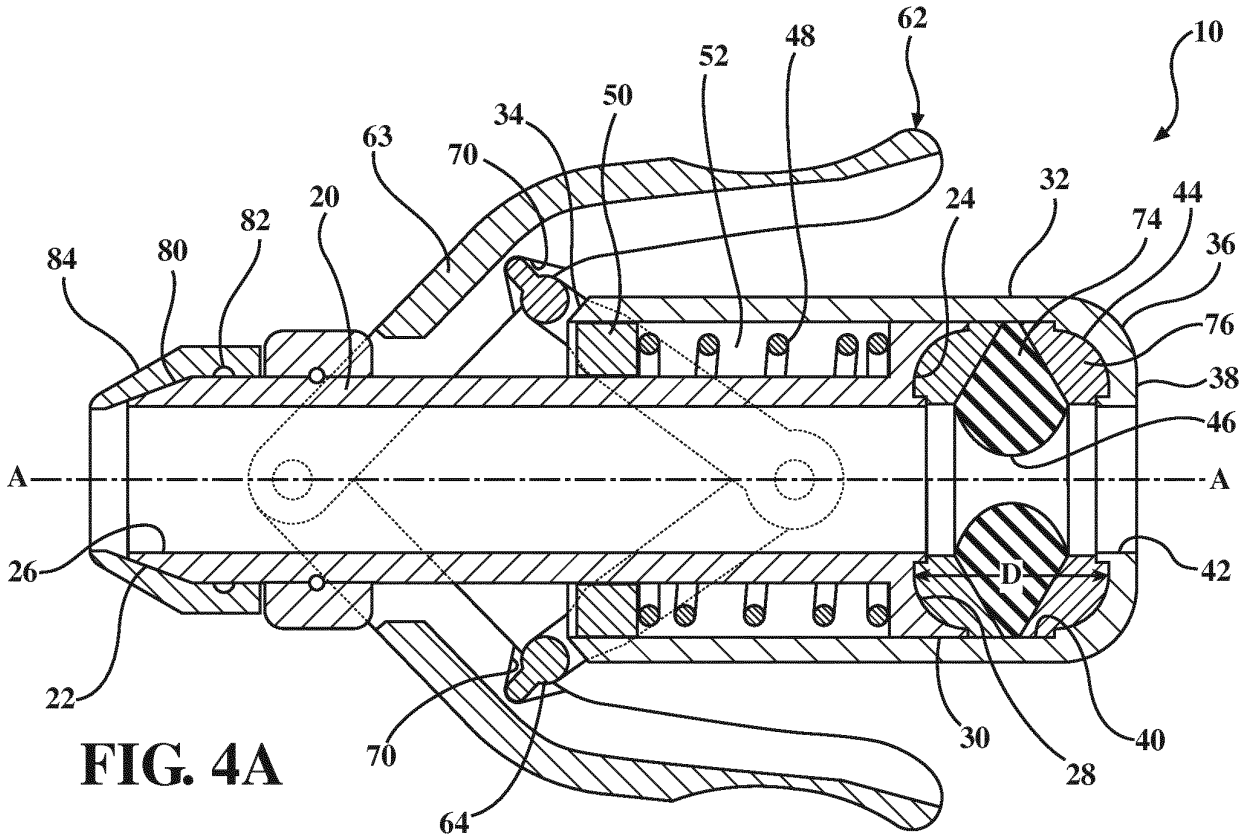
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FIG. 4A

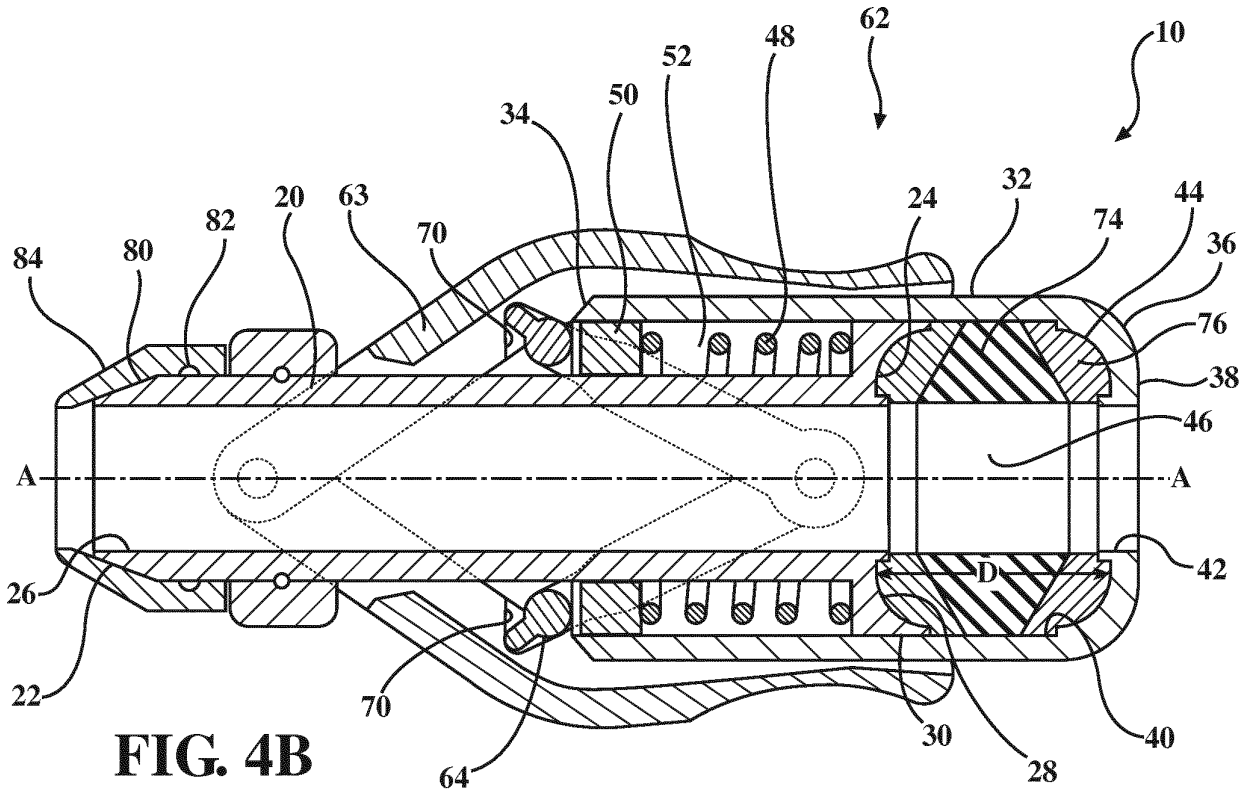
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FIG. 4B

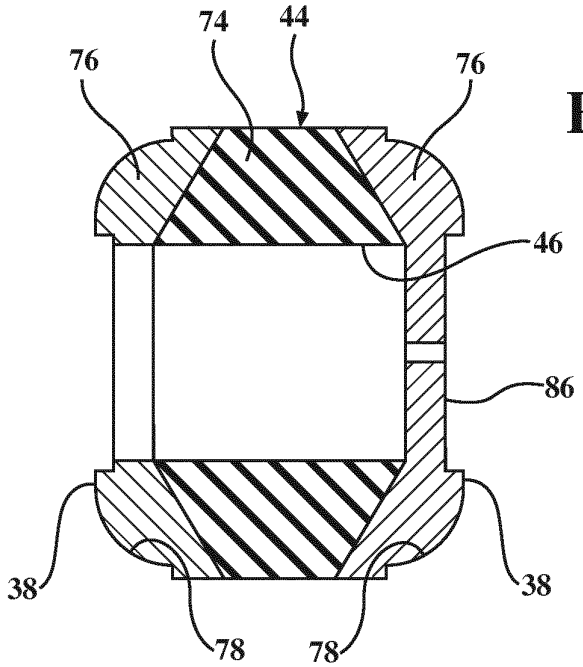
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FIG. 5

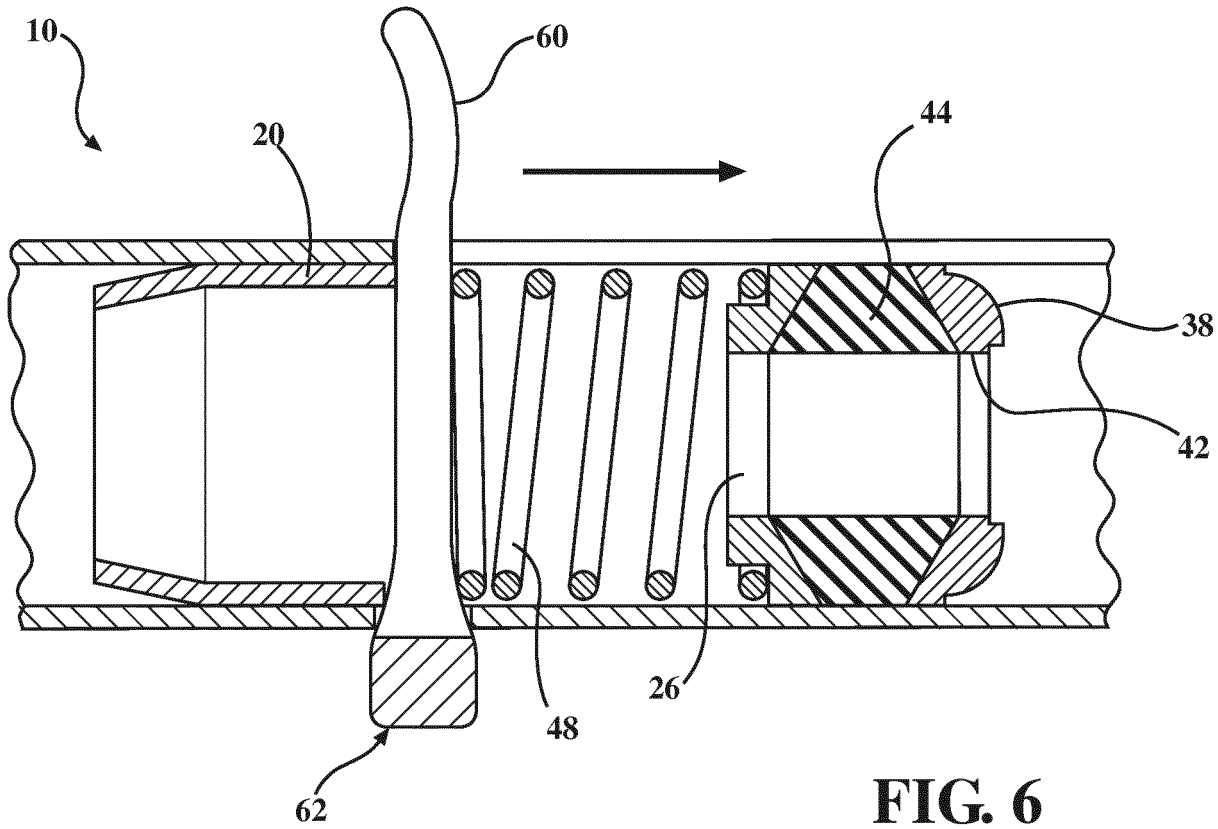

FIG. 6

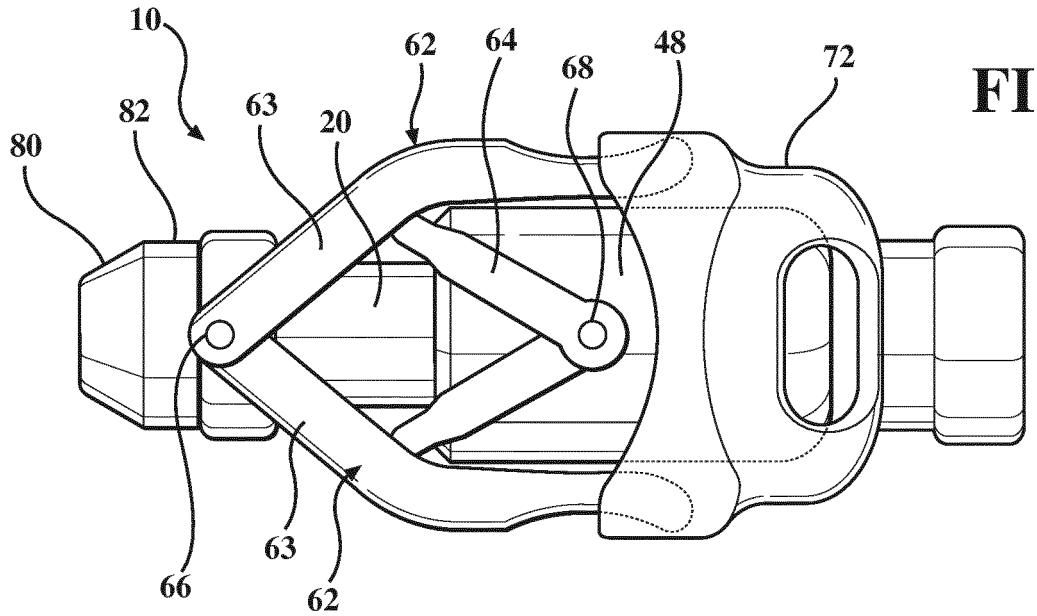

FIG. 7

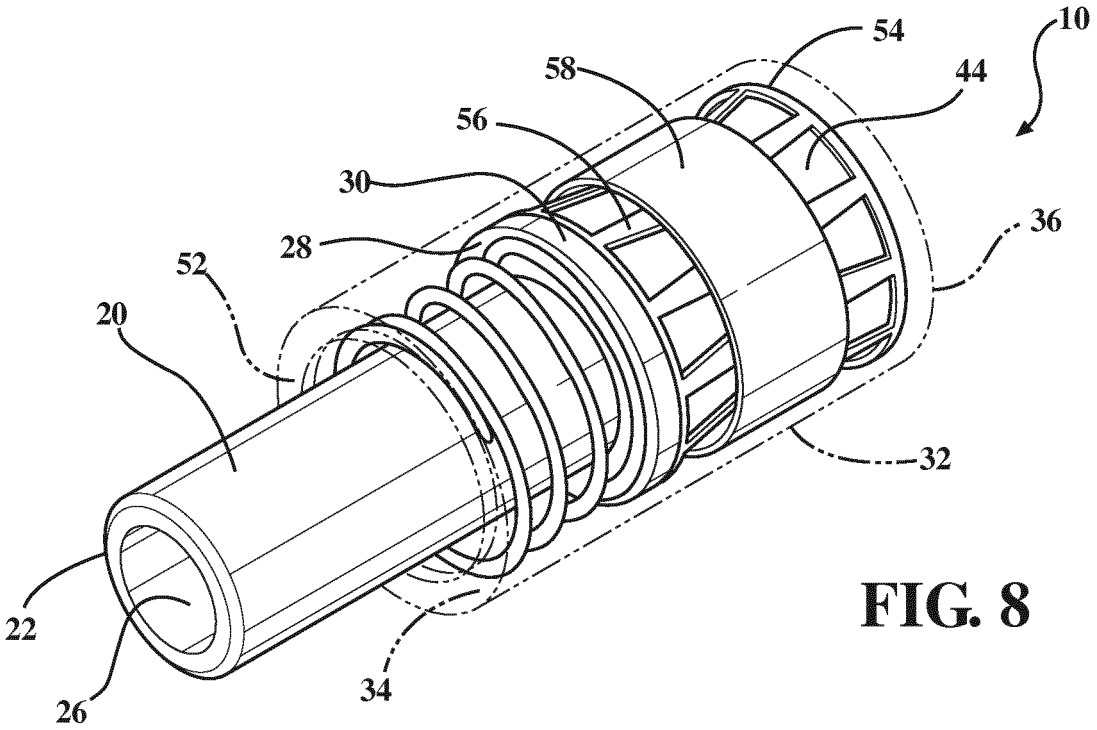
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FIG. 8

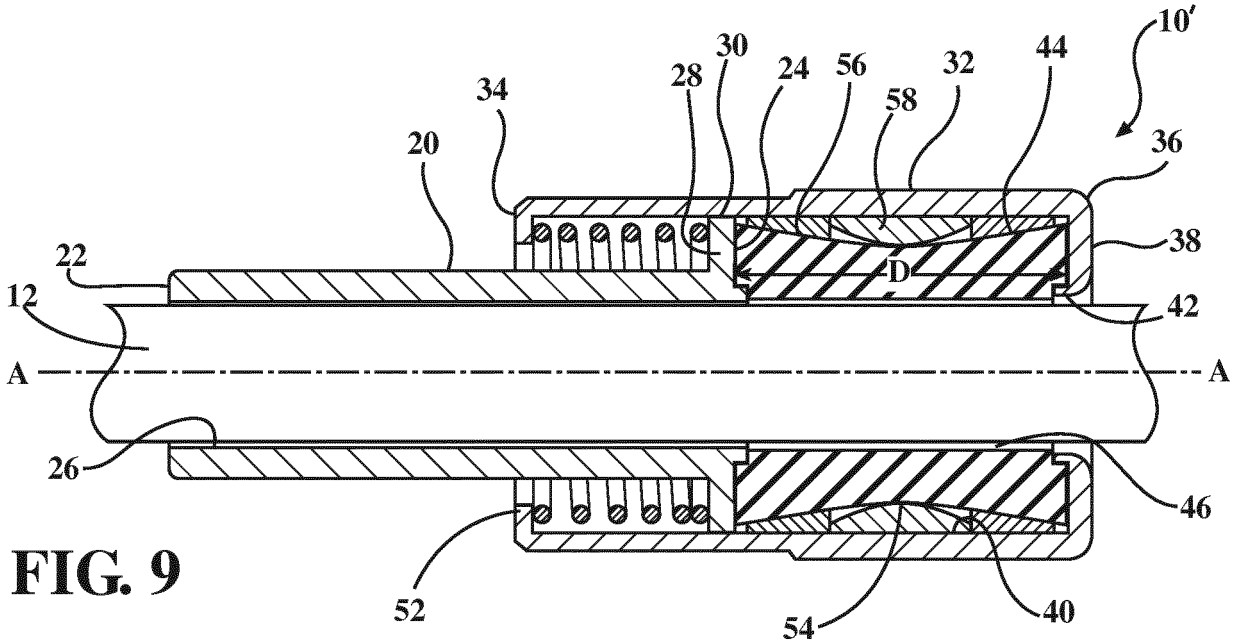
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FIG. 9

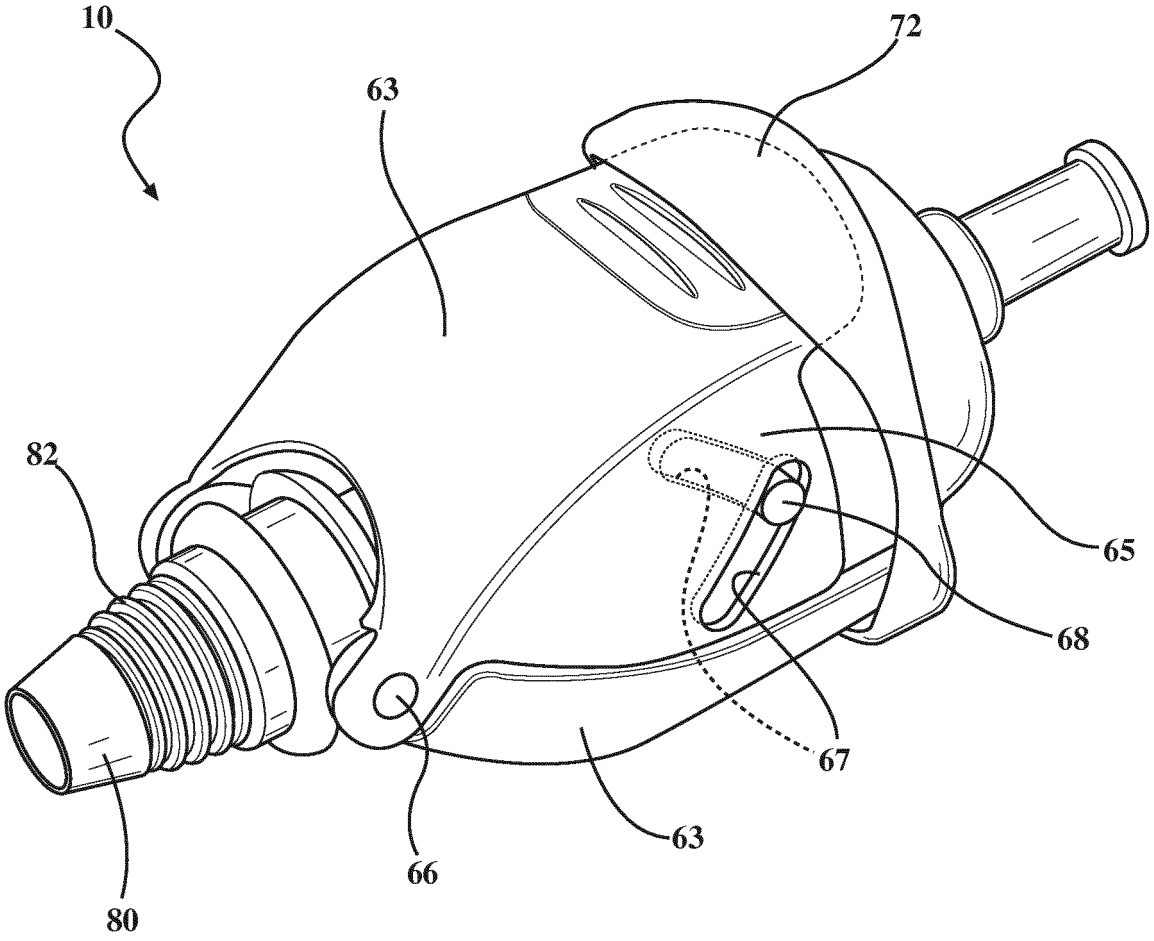

FIG. 10

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 6572590 B1 **[0004]**
- US 6458103 B1 **[0004]**
- US 20110264105 A **[0004]**